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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,796	05/04/2005	Yoshitaka Miyakawa	38331-0006	6927

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EXAMINER	
LIETO, LOUIS D	
ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 12/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/533,796	MIYAKAWA ET AL.	
	Examiner	Art Unit	
	Louis D. Lieto	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/04/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *E-mail*.

DETAILED ACTION

Claims 1-9 are pending and currently under consideration.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. However, applicant should note that an English translation of the foreign priority documents has not been received.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1,2, 4,and 5are rejected under 35 U.S.C. 102(a) as being anticipated by Miyakawa et al. {Miyakawa et al. (Nov. 9, 2002) Blood 100:601a}.

It is noted that the reference of Miyakawa et al shares co-authorship with the inventor of the instant application. However, the reference of Miyakawa et al was also co-authored by Makoto Monnai, Masashi Tomisawa, Mamoru Ito, Norikazu Tamaoki, and Tasuji Nomura, who are not listed as inventors of the instant invention. Therefore the

reference of Miyakawa et al. was written by a different inventive entity than that of the instant invention. Further, Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Miyakawa et al. provides guidance on the establishment of a human multiple myeloma model using a NOG mouse (Abstract). Miyakawa et al. teaches inoculating NOG mice with cells from the U266 myeloma cell line, which led to engraftment, proliferation, and invasion of healthy tissue (Abstract). Therefore, by teaching all the limitations of the claims as written, Miyakawa et al. clearly anticipates the instant invention as claimed.

Claims 1,3,4,6,7, and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent Application No: 2003/0182671 (9.25.2003), priority to (10.25.2001), hereafter referred to as Ito et al.

Ito et al. provides guidance on an immunodeficient mouse (NOG mouse) suitable for engraftment of tumor cells (Abstract). In the NOG mouse, human tumors can be engrafted and proliferated, and an animal model of a human tumor can be obtained by transplanting tumor cells to the mouse of the present invention. For example, the administration of the human tumor cells causes the proliferation thereof inside the mouse body, and thus a mouse having a human tumor can be obtained. Examples of the cells to be used in this case include subcultured lines of human tumor in a conventional nude mouse, and cell lines derived from HTLV-1 leukemia such as ED-40515 (-), MT-1 and TL-Om1 (pgph 77). Further, Ito et al. teaches the transplant of the human tumor cell

line, LM-2-JCK into NOG mice (Example 5, pgphs 185-195). LM-2-JCK was a cell line that was established from lymphoblast lymphoma of a 13-year-old female patient and maintained by successive heterografts to nude mice. It has been reported that though LM-2JCK expresses T-cell antigen CD4 and CD5, it does not express other cell antigens including antibodies. Finally, Ito et al. teaches that the mouse tumor model can be used for the "screening of screening therapeutic agents." (pgph 236). Therefore, by teaching all the limitations of the claims as written, Ito et al. clearly anticipates the instant invention as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2, 5, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Application No: 2003/0182671 (9.25.2003), priority to (10.25.2001), hereafter referred to as Ito et al, further in view of Blase et al. {Blase et al. (1995) Int. J. Cancer 60: 860-866}.

Ito et al. provides guidance on an immunodeficient mouse (NOG mouse) suitable for engraftment of tumor cells (Abstract). In the NOG mouse, human tumors can be engrafted and proliferated, and an animal model of a human tumor can be obtained by transplanting tumor cells to the mouse of the present invention. For example, the administration of the human tumor cells causes the proliferation thereof inside the mouse

body, and thus a mouse having a human tumor can be obtained. Examples of the cells to be used in this case include subcultured lines of human tumor in a conventional nude mouse, and cell lines derived from HTLV-1 leukemia such as ED-40515 (-), MT-1 and TL-Oml (pgph 77). Further, Ito et al. teaches the transplant of the human tumor cell line, LM-2-JCK into NOG mice (Example 5, pgphs 185-195). LM-2-JCK was a cell line that was established from lymphoblast lymphoma of a 13-year-old female patient and maintained by successive heterografts to nude mice. It has been reported that though LM-2JCK expresses T-cell antigen CD4 and CD5, it does not express other cell antigens including antibodies. Finally, Ito et al. teaches that the mouse tumor model can be used for the "screening of screening therapeutic agents." (pgph 236). Ito et al. does not teach administering U266 cells to a NOG mouse.

Blase et al. supplements the guidance of Ito et al. by teaching the administration of U266 cells to SCID mice to study the disseminative capacity of these cells (Abstract; pg. 860-861, Materials and Methods).

Based on the guidance provided by Blase et al. it would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to modify the teachings of Ito et al. by administering human U266 tumor cells to the NOG mouse in order to make a U266 tumor model.

A practitioner in the art would have been motivated to combine the teachings of Blase et al. and Ito et al. to study the disseminative capacity of U266 cells in a NOG background mouse.

The person of ordinary skill in the art would have had a reasonable expectation of success because Ito et al. teaches that the NOG mouse provides a suitable host for any human tumor cell line.

No claims allowed.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Lou Lieto whose telephone number is (571) 272-2932. The examiner can normally be reached on Monday-Friday, 9am-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Patent applicants with problems or questions regarding electronic images that can be viewed in the PAIR can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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